REMARKS

Status of the Claims

Claims 1, 4, 6, 7, 9-12, 15, 17, 18, 33, 36, 42, 43, 46, 49, 50 and 52-58 are in the application.

Claims 1, 6, 7, 12, 17, 33, 46, 49, 53-54 and 56 are rejected.

Claims 1, 4, 7, 9-12, 15, 17, 18, 33, 36, 42, 43, 46, 49, 50, 52-58 are objected to.

By way of this amendment, claims 1, 7, 12 and 33 have been amended, claims 4, 9-11, 15, 18, 36, 42, 43, 46, 49, 50, 52-54 and 56-58 have been canceled, and new claim 59-92 have been added.

Upon entry of this amendment, claims 1, 6, 7, 12, 17, 33, 55 and 59-91 will be pending.

Summary of the Amendment

The claims have been amended to clarify the subject matter of the claims and to facilitate examination by grouping related claims sequentially. Claims 1, 7, 12 and 33, which are each independent claims, remain pending and have been amended. Claims 6, 17 and 55 also remain pending. Claims 4, 9-11, 15, 18, 36, 42, 43, 46, 49, 50, 52 and 56-58 have been canceled in favor of new claims 59-91. Any subject matter not included in new claims 59-91 which was either canceled from claims 1, 6, 7, 12, 17, 33 and 55 or the subject of canceled claims 4, 9-11, 15, 18, 36, 42, 43, 46, 49, 50, 52 and 56-58 has been canceled without prejudice. Each of claims 1, 7, 12 and 33 as amended, claims 6, 17 and 55 in view of the amendments to the claims from which they depend, and new claims 59-91 read on the elected species.

No new matter has been added.

Claim 1

Claim 1 as amended refers to a pyrogen free composition that comprises a plasmid that comprises both a nucleotide sequence that encodes DR5 and a nucleotide sequence that encodes an influenza antigen, an HIV-1 antigen or an HSV antigen.

Claim 1 has been amended to delete references to non-elected immunomodulating proteins. As amend, claim 1 recites that that the immunomodulating protein is DR5, the elected species.

Claim 1 has also been amended to add "an influenza antigen" to the list of immunogens set forth in the claim 1. This subject matter added to claim 1 was previously set forth in claim 46, now canceled.

Support for the amendment of claim 1 is found throughout the specification and claims as originally filed.

Claim 7

Claim 7 as amended refers to a method of inducing cytotoxic T cell responses in an individual against a pathogen antigen which comprises intramuscular administration of a composition that comprises a plasmid that comprises both a nucleotide sequence that encodes DR5 and a nucleotide sequence that encodes a pathogen antigen.

Claim 7 has been amended to delete references to non-elected immunomodulating proteins. As amend, claim 7 recites that that the immunomodulating protein is DR5, the elected species.

Claim 7 has also been amended to no longer recite that the compositions are "pyrogen free".

Support for the amendment of claim 7 is found throughout the specification and claims as originally filed.

Claim 12

Claim 12 as amended refers to a pyrogen free composition that comprises two plasmids, one plasmid that comprises a nucleotide sequence that encodes DR5 and one plasmid that comprises a nucleotide sequence that encodes an influenza antigen, an HIV-1 antigen or an HSV antigen.

Claim 12 has been amended to delete references to non-elected immunomodulating proteins. As amend, claim 12 recites that that the immunomodulating protein is DR5, the elected species.

Claim 12 has also been amended to recite that the immunogen is

> selected from the group consisting of an influenza antigen, an HIV-1 antigen and a HSV antigen.

The subject matter with respect to "an influenza antigen" was previously set forth in claim 46, now canceled. The subject matter with respect to "an HIV-1 antigen and an HSV antigen" added in claim 12 was not present in the previously pending claims. However, the support for this subject matter is found throughout the specification and claims as originally filed, and the nature of the added subject matter is similar to and consistent with subject matter that has been indicated to be allowable with respect to claim 1.

Support for the amendment of claim 12 is found throughout the specification and claims as originally filed.

Claim 33

Claim 33 as amended refers to a method of inducing a cytotoxic T cell response in an individual against a pathogen antigen which comprises intramuscular administration of a composition that comprises two plasmids: one plasmid that comprises a nucleotide sequence that encodes DR5 and one plasmid that comprises a nucleotide sequence that encodes a pathogen antigen.

Claim 33 as been amended to delete references to non-elected immunomodulating proteins. As amended, claim 33 recites that the immunomodulating protein is DR5, the elected species.

Claim 33 has also been amended to no longer recite that the compositions are "pyrogen free".

Claim 33 has been additionally amended to clarify the subject matter of the claim to more clearly state that the composition administered according to the claimed method comprises "two plasmids".

Support for the amendment of claim 33 is found throughout the specification and claims as originally filed.

New claims 59-64

New claims 59-64 each directly or indirectly depend from claim 1 and accordingly refer to a pyrogen free composition that comprises a plasmid that comprises both a nucleotide

sequence that encodes DR5 and a nucleotide sequence that encodes an influenza antigen, an HIV-1 antigen or an HSV antigen or injectable compositions comprising the same.

New claims 59, 61 and 63 each depend from claim 1 and provides that immunogen is one of the three immunogens recited in claim 1, i.e. an influenza antigen (claim 59), an HIV antigen (claim 61), and an HSV antigen (claim 63).

New claims 60, 62 and 64 depend from claims 59, 61 and 63, respectively, and provide injectable compositions comprising the pyrogen free composition of claims 59, 61 and 63, respectively.

New claim 59 contains subject matter of canceled claim 46.

New claim 60 contains subject matter subject matter with respect to "injectable compositions" which comprise a plasmid that includes nucleic acid sequences that encode an influenza antigen". The specific subject matter was not present in the previously pending claims. However, the support for this subject matter is found throughout the specification and claims as originally filed, and the nature of the added subject matter is similar to and consistent with subject matter related to other antigens which have been indicated to be allowable.

New claim 61 is identical to canceled claim 4.

New claim 62 contains subject matter that is included in claim 6.

New claim 63 contains subject matter that is included in claim 9.

New claim 64 contains subject matter that is included in claim 10.

Support for new claims 59-64 is found throughout the specification and claims as originally filed.

New claims 65-75

New claims 65-75 each directly or indirectly depend from claim 7 as amended and accordingly refer to a method of inducing cytotoxic T cell responses in an individual against a pathogen antigen which comprises intramuscular administration of a composition that comprises a plasmid that comprises both a nucleotide sequence that encodes DR5 and a nucleotide sequence that encodes a pathogen antigen.

New claim 65 provides that the composition administered in the method of claim 7 is pyrogen free. As noted above, claim 7 was amended to delete the limitation that the compositions is pyrogen free. New claim 65 corresponds to the subject matter of claim 7 prior to that deletion.

New claims 66 and 67 provides that methods in which the pathogen antigen is a "viral antigen". New claim 66 is dependent on claim 7 and provides that the pathogen antigen encoded by the plasmid administered to the individual is a "viral antigen". New claim 67 is dependent on new claim 66 and provides that the compositions is pyrogen free.

New claims 68-75 further limit the pathogen antigen referred to in claim 7.

New claim 68 is dependent on claim 7 and provides that the pathogen antigen encoded by the plasmid administered to the individual is an influenza antigen, an HIV-1 antigen or an HSV antigen. New claim 69 is dependent on new claim 68 and provides that the compositions is pyrogen free.

New claims 70, 72 and 74 each depend from claim 7 and provides that the pathogen antigen encoded by the plasmid administered to the individual is an influenza antigen (claim 70), an HIV antigen (claim 72), and an HSV antigen (claim 74). New claims 71, 73 and 75 depend from new claims 70, 72 and 74, respectively, and provide provides that the compositions administered to the individual in the method of claims 70, 72 and 74, respectively, are pyrogen free.

The specific subject matter of new claims 66 and 67 was not present in the previously pending claims. However, the support for this subject matter is found throughout the specification and claims as originally filed, and the nature of the added subject matter is somewhat similar to and consistent with subject matter in claim 55 which has been indicated to be allowable.

The specific subject matter of new claims 68-75 was not present in the previously pending claims. However, the support for this subject matter is found throughout the specification and claims as originally filed, and the nature of the added subject matter is

somewhat similar to and consistent with subject matter other claims which have been indicated to be allowable.

Support for new claims 65-75 is found throughout the specification and claims as originally filed.

New claims 76-81

New claims 76-8 each directly or indirectly depend from claim 12 (which has been amended to recite that the pathogen antigens encoded by the nucleic acid sequence included in one of the two plasmid is "an influenza antigen, an HIV-1 antigen or an HSV antigen") and accordingly refer to a pyrogen free composition that comprises two plasmids, one plasmid that comprises a nucleotide sequence that encodes DR5 and one plasmid that comprises a nucleotide sequence that encodes an influenza antigen, an HIV-1 antigen or an HSV antigen.

New claims 76, 78 and 80 each depend from claim 12 and provide that the immunogen is one of the three immunogens recited in amended claim 12, i.e. an influenza antigen (claim 76), an HIV antigen (claim 78), and an HSV antigen (claim 80).

New claims 77, 79 and 81 depend from new claims 76, 78 and 80, respectively, and provide injectable compositions comprising the pyrogen free composition of claims 76, 78 and 80, respectively.

The subject matter of new claim 76 includes subject matter in canceled claim 49.

New claim 78 is identical to canceled claim 15.

The subject matter of new claim 80 includes subject matter in canceled claim 42.

The subject matter of new claim 81 includes subject matter in canceled claim 43.

The specific subject matter of new claims 77 and 79 was not present in the previously pending claims. However, the support for this subject matter is found throughout the specification and claims as originally filed, and the nature of the added subject matter is somewhat similar to and consistent with subject matter other claims which have been indicated to be allowable.

Support for new claims 76-81 is found throughout the specification and claims as originally filed.

New claims 82-91

New claims 82-91 each directly or indirectly depend from claim 33 and accordingly refer to a method of inducing a cytotoxic T cell response in an individual against an immunogen that is a pathogen antigen which comprises intramuscular administration of a composition that comprises two plasmids, one plasmid that comprises a nucleotide sequence that encodes a DR5 and one plasmid that comprises a nucleotide sequence that encodes a pathogen antigen.

New claim 82 provides that the composition administered in the method of claim 33 is pyrogen free. As noted above, claim 33 was amended to delete the limitation that the compositions is pyrogen free. New claim 82 corresponds to the subject matter of claim 33 prior to that deletion.

Similarly, new claim 83 provides that the composition administered in the method of claim 55 is pyrogen free. New claim 83 corresponds to the subject matter of claim 55 prior to that deletion from claim 33 of the limitation that the compositions is pyrogen free.

New claims 84-91 further limit the pathogen antigen referred to in claim 33.

New claim 84 is dependent on claim 33 and provides that the pathogen antigen encoded by the plasmid administered to the individual is an influenza antigen, an HIV-1 antigen or an HSV antigen.

New claim 85 is dependent on new claim 84 and provides that the compositions is pyrogen free.

New claims 86, 88 and 90 each depend from claim 33 and provides that the pathogen antigen encoded by the plasmid administered to the individual is an influenza antigen (claim 86), an HIV antigen (claim 88), and an HSV antigen (claim 90). New claims 87, 89 and 91 depend from new claims 86, 88 and 90, respectively, and provide provides that the compositions administered to the individual in the method of claims 86, 88 and 90, respectively, are pyrogen free.

The subject matter of new claims 82 and 83 includes subject matter in claim 33 and 55 prior to the amendment of those claims.

The subject matter of new claims 84 and 85 includes subject matter in canceled claim 36 and 52.

The subject matter of new claim 86 is similar to canceled claim 50 and 52.

New claim 87 is identical to canceled claim 50 and 52.

The subject matter of new claim 88 is similar to canceled claim 36.

New claim 89 is identical to canceled claim 36 was not present in the previously pending claims. However, the support for this subject matter is found throughout the specification and claims as originally filed, and the nature of the added subject matter is somewhat similar to and consistent with subject matter other claims which have been indicated to be allowable.

Support for new claims 82-91 is found throughout the specification and claims as originally filed.

Claim Rejection Under 35 U.S.C. § 102

Claims 12, 17 and 54 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,417,328 (hereinafter Alnemri). Claim 1, 6 and 53 had been similarly rejected prior to the amendment dated March 15, 2011 and the rejection was withdrawn in view of the amendment by which specific immunogens were recited.

By way of this amendment, claim 1 (and accordingly dependent claim 6) has been made broader by the addition of "an influenza antigen" as a possible antigen. This subject matter was imported from canceled claim 46 which was objected to.

By way of this amendment, claim 12 has been amended to specifically recite a list of immunogens, i.e. "an influenza antigen, an HIV antigen and an HSV antigen".

Claim 54 have been canceled and the rejection as applied to claim 54 is moot.

In view of the amendment to claim 12, the rejection of claims 12, 17 and 54 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,417,328 (hereinafter Alnemri) as applied to claims 12 and 17 is obviated.. Applicants respectfully request that the rejection of claims 12, 17 and 54 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,417,328 (hereinafter Alnemri) as applied to claims 12 and 17 be withdrawn.

Claim Rejection Under 35 U.S.C. § 103 for elected species

Claims 12, 17 and 54 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,417,328 (hereinafter Alnemri) in view of U.S. Patent No. 5,693,622 (hereinafter Wolff). Claim 1, 6 and 53 had been similarly rejected prior to the amendment dated March 15, 2011 and the rejection was withdrawn in view of the amendment by which specific immunogens were recited.

By way of this amendment, claim 1 (and accordingly dependent claim 6) has been made broader by the addition of "an influenza antigen" as a possible antigen. This subject matter was imported from canceled claim 46 which was objected to.

By way of this amendment, claim 12 (and accordingly dependent claim 17) has been amended to specifically recite a list of possible immunogens, i.e. "an influenza antigen, an HIV antigen and an HSV antigen".

Claim 54 have been canceled and the rejection as applied to those claims is moot..

In view of the amendment to claim 12, the rejection of claims 12, 17 and 54 under 35 U.S.C. 103(a) as being unpatentable over Alnemri in view of Wolff, as applied to claims 12 and 17 is obviated.. Applicants respectfully request that the rejection of claim 12, 17 and 54 under 35 U.S.C. 103(a) as being unpatentable over Alnemri in view of Wolff, as applied to claims 12 and 17 be withdrawn.

Claim Rejections Under 35 U.S.C. § 112 – second paragraph

Claim 53 has been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 53 has been canceled and the rejection is moot. Applicants respectfully request that the rejection under 35 U.S.C. 112, second paragraph, be withdrawn.

Claim Rejections Under 35 U.S.C. § 112 – fourth paragraph

Claim 53 has been rejected under 35 U.S.C. 112, 4th paragraph, as being in improperly dependent form for failing to further limit the subject matter of the claim upon which it depends, or for failing to include all the limitations of the claim upon which it depends.

Claim 53 has been canceled and the rejection is moot. Applicants respectfully request that the rejection under 35 U.S.C. 112, fourth paragraph, be withdrawn.

Duplicate Claims

The Official Action notes on page 7 that

> should amended claim 7 be found allowable, claim 33 and claim 56 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof;

and

> should claim 55 be found allowable, claim 57 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof;

and

> should claim 52 be found allowable, claim 58 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof.

Regarding claims 7 and 33, claim 33 has been amended to more clearly refer to two plasmids including one that encodes DR5 and one that encodes a pathogen antigen. Claim 7 refers to the administration of a composition comprising a plasmid including a nucleotide sequence that encodes DR5 and a nucleotide sequence that encodes a pathogen antigen. Claims 7 and 33 refer to different subject matter and are not substantially duplicate claims.

Regarding claims 55 and 57, claim 57 has been canceled and the issue is moot.

Regarding claims 52 and 58, claims 52 and 58 have been canceled and the issue is moot.

Claim Objections

The Official Action indicates that the objection to pending claims 1, 4, 6, 7, 9, 12, 15, 17, 18, 33, 36, 42, 43,46, 49, 50 and 52-58 for continuing to recite non elected subject matter is maintained.

Claims 1, 7, 12 and 33 as amended herein, and claim 6, 17 and 55 remain pending. Claims 4, 9, 15, 18, 36, 42, 43, 46, 49 50, 52, and 56-58 have been canceled in favor of new claims 59-91.

Claims 1, 7, 12 and 33 have each been amended to delete reference to non-elected subject matter. Accordingly, claims 6, 17 and 55 are also limited to the elected species only. Each of

new claims 59-91 depend directly or indirectly from one of claims 1, 7, 12 and 33 and are therefore also restricted to the elected species.

Claims 15, 18, 42 and 43 have been objected to as being dependent upon a rejected base claim, but would be allowable based on the elected species of DR5 as the immunomodulating protein if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

In addition, the Official Action indicates that, if claims 1, 4,6 7, 9, 11, 15,18, 33, 36, 42, 43, 46, 49, 50, 52, and 55-58 are limited the elected subject matter of DR5, and if all claims dependent on rejected claims 12, 17, or 54 are rewritten in independent form, the subject matter of claims 1, 4, 6, 7, 9, 11, 15, 18, 33, 36, 42, 43, 46, 49, 50, 52 and 55-58 would be considered free of the prior art of record and allowable.

Applicants have amended claims 1, 7, 12 and 33 and with the exception of claims 6, 17 and 55 canceled the other claims in favor of new claims 59-91 in an attempt to embrace the subject matter deemed free of the prior art of record and allowable as set forth above in claims that set forth the subject matter in a more systematic and organized manner. Applicants note that, in preparing the claims, some changes have been introduced so that claims 1, 6, 7, 12, 17 33 and 55 and new claims 59-91 are not identical in all respects to the previous claims. Some subject matter not included in the earlier claim set as noted above has been added. Applicants believe that the newly added subject matter is consistent with the scope of allowable subject matter indicated in the Official Action. Thus, while the subject matter of the claims following entry of this amendment is not identical to the claims indicated as allowable, the differences are not believed to raise new issues of patentability. In each instance, the pending claims are limited to the elected species.

Claim 1 as objected to has been amended to add subject matter from claim 46, which was also objected.

Claim 4 as objected to has been canceled and is now presented as new claim 59.

Claim 6 as objected to has changed in scope in view of the amendment of claim 1 in which subject matter from claim 46 was added to claims 1.

Claim 7 as objected to has been amended to delete reference to "pyrogen free", thereby broadening the scope of that aspect of the claim. New claim 65 corresponds to claim 7 without the non elected subject matter.

Claims 9 and 10 as objected to has been canceled in favor of new claims 63 and 64, respectively, which refer more broadly to HSV antigens than canceled claim 9.

Claim 11 as objected to has been canceled and is now presented as new claim 74.

Claim 15 as objected to has been canceled and is now presented as new claim 78.

Claims 18 as objected to has been canceled and is now presented as new claim 82.

Claims 33 as objected to is now presented as new claim 82.

Claim 36 as objected to has been canceled and is now presented as new claim 88.

Claims 42 and 43 as objected to has been canceled in favor of new claims 80 and 81, respectively, which refer more broadly to HSV antigens than canceled claim 42.

Claim 46 as objected to has been canceled and the subject matter of claim 46 has bee added to amended claim 1.

Claim 49 as objected to has been canceled and the subject matter of claim 49 has bee added to amended claim 12.

Claims 50 and 52 as objected have been canceled and are now presented as new claim 78.

Claim 55 as objected is now presented as new claim 83.

Claim 56 as objected correspond to amended claim 33.

Claim 57 as objected correspond to claim 55 in view of the amendment to claim 33.

Claim 58 as objected correspond to amended claim 86.

Applicants respectfully urge that claims 1, 6, 7, 12, 17, 33 and 55 and new claims 59-91 are in condition for allowance.

Claim Rejection Under 35 U.S.C. § 103 for non-elected species

Claims 33, 46, 49, and 56 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,916,879 (1999), hereafter referred to as Webster, in view of US Patent No. 5,990,301 (1999), hereafter referred to as Colpan et al.. Applicants note that this rejection was withdrawn with respect to claims 1 and 6 in view of the previous amendment of

claim 1. As stated above, claim 1 has been amended to cancel the limitation added by the previous amendment.

Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prayaga et al. (1997) Vaccine, Vol. 15 (12/13), 1349 1352, in view of U.S. Patent No. 5,916,879 (1999), hereafter referred to as Webster, and US Patent No. 5,990,301 (1999), hereafter referred to as Colpan et al.

Claims 1, 7, 12 and 33 have been amended to recite only the elected species. Claims 6, 17 and 55 and new claims 59-91 each directly or indirectly depend from one of claims 1, 7, 12 and 33 and accordingly as likewise restricted.

The rejection of claims 33, 46, 49, and 56 under 35 U.S.C. 103(a) as being unpatentable over Webster in view of Colpan et al and the rejection of claims 1 and 6 under 35 U.S.C. 103(a) as being unpatentable over Prayaga in view of Webster and Colpan et al are thereby moot.

Applicants respectfully request that the rejection of claims 33, 46, 49, and 56 under 35 U.S.C. 103(a) as being unpatentable over Webster in view of Colpan et al as applied to claim 33 be withdrawn.

Applicants respectfully request that the rejection of claims 1 and 6 under 35 U.S.C. 103(a) as being unpatentable over Prayaga in view of Webster and Colpan et al be withdrawn.

Conclusion

Claims 1, 6, 7, 12, 17, 33, 55 and 59-91 are in condition for allowance. A notice of allowance is earnestly solicited. Applicants invite the Examiner to contact the undersigned at 610.640.7855 to clarify any unresolved issues raised by this response.

The Commissioner is hereby authorized to charge any deficiencies of fees and credit of any overpayments to Deposit Account No. 50-0436.

Respectfully submitted,

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